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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,855	09/05/2003	Hans Binz	PF 57 CONT 4	7263

25666 7590 09/08/2006

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EXAMINER

SALIMI, ALI REZA

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/655,855

Applicant(s)

BINZ ET AL.

Examiner

A R. Salimi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/721,979.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/5/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed 07/10/2006. Claims 28-32 have been added. Claims 1-32 are currently pending.

Election/Restrictions

Applicant's election with traverse of Group VII (Claims 27-32) in the reply filed on 07/10/2006 is acknowledged. However, since no argument was set forth by the Applicants, the election was treated as an Election **without** traverse. Hence, Claims 1-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected. Claims 27-32 are considered.

Applicants are reminded to cancel the claims to the non-elected Group(s).

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the earlier filed application(s) in the first sentence of the specification (37 CFR 1.78).

Claim Rejections - 35 USC § 112

Claims 27, 31-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of respiratory syncytial virus (RSV), does not reasonably provide enablement for prevention of RSV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification has some data

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regarding induction of antibodies which is categorized as an induction in immune response and treatment of RSV. However, the specification has no teaching regarding a subsequent exposure of the natural host to the virus and the level of protective immunity. In other words the specification has not shown any protective response absent undue experimentation.

Applicants have general statements regarding the prevention of RSV upon administration of SEQ ID NO: 13. However with regard to an unpredictable field, this does not constitute an adequate disclosure. See *Fiers v. Revel* (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001-1007). For example, the CAFC stated that “It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement.” (See page 1005 of the decision). In the instant case the specification does not teach or provide any guidance for prevention of RSV. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. The Applicants cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

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is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-12 of U.S. Patent No. 6,616,930 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because overlap in scope. In addition, the subject matter of the claims are so closely related that would incorporate overlap species and/or claim 27 is so broadly drafted that would incorporate any and all species that may or may not be present in 6,616,930 Patent.

Subject matter Free of Prior art

Claims 27-32 are deemed free of prior art, given failure of the prior art to teach or reasonably suggest the SEQ ID NO: 13. The closest art identified is Lawrence et al, Journal of General Microbiology, 1991, pages 1911-1921, and post filing article by Nguyen et al, Gene, 1998, pages 93-101.

No claims are allowed.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

08/30/2006


ALI R. SALIMI
PRIMARY EXAMINER